No. 2014-1476

United States Court of Appeals
for the
Federal Circuit

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD.,

Plaintiffs-Appellants,

– against –

LUPIN PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; MYLAN PHARMACEUTICALS INC.; APOTEX INC.; and APOTEX CORP.,

Defendants-Appellees,

– and –

WATSON LABORATORIES, INC.,

Defendant.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
CIV. NO. 13-121, JUDGE ARENDA L. WRIGHT ALLEN

JOINT BRIEF FOR DEFENDANTS-APPELLEES LUPIN PHARMACEUTICALS, INC., APOTEX INC., and APOTEX CORP.

STEPHEN R. AUTEN
RICHARD T. RUZICH
IAN SCOTT
TAFT STETTINIUS & HOLLISTER LLP
111 E. Wacker Drive, Suite 2800
Chicago, Illinois 60601
(312) 527-4000

Attorneys for Defendants-Appellees Apotex Inc. and Apotex Corp.

DOUGLASS C. HOCHSTETLER
KELLEY DRYE & WARREN LLP
333 West Wacker Drive
Chicago, Illinois 60606
(312) 857-7070

BETH D. JACOB
CLIFFORD KATZ
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178
(212) 808-7800

Attorneys for Defendant-Appellee Lupin Pharmaceuticals, Inc.

CERTIFICATE OF INTEREST

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

G.D. Searle LLC v. Lupin Pharmaceuticals, Inc.

No. 14-1476

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Appellee Lupin Pharmaceuticals, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Lupin Pharmaceuticals, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Not applicable

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Lupin, Ltd.

4. ☐ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Kelley Drye & Warren LLP, Douglass Hochstetler, Beth Jacob, Clifford Katz, Joseph Wilson, Barrett McVary, David Yohannan, and Stephen Freeland

September 25, 2014
Date

/s/Clifford Katz
Signature of counsel

Clifford Katz
Printed name of counsel

Please Note: All questions must be answered

cc: _____

Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

G.D. SEARLE LLC, et al. v. LUPIN PHARMACEUTICALS, INC., et al.

No. 14-1476

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Appellees Apotex Inc. and Apotex Corp. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Apotex Inc. and Apotex Corp.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Apotex Inc. is wholly owned by Apotex Pharmaceutical Holdings Inc., which itself is wholly owned by Apotex Holdings Inc. Apotex Corp. is wholly owned by Aposherm Inc., which is itself wholly owned by Apotex Holdings Inc. None of the above-referenced firms are publicly traded companies.

4. ☑ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Richard Ruzich, Stephen Auten, and Ian Scott with Taft Stettinius & Hollister LLC and Richard Ottinger with Vandeventer Black LLP

September 25, 2014
Date

/s/ Richard T. Ruzich
Signature of counsel

Richard T. Ruzich
Printed name of counsel

Please Note: All questions must be answered

cc: _____

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

STATEMENT OF RELATED CASE

This appeal is related to the following earlier appeal: *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2007-1271, 518 F.3d 1353 (Fed. Cir. 2008) (*Pfizer I*). The composition of the panel in the prior appeal was: Paul R. Michel, Chief Judge, Timothy B. Dyk, Circuit Judge, and Matthew F. Kennelly, District Judge, United States District Court for the Northern District of Illinois, sitting by designation. In *Pfizer I*, this Court held that the asserted claims of U.S. Patent No. 5,760,068 (the '068 patent) were invalid for obviousness-type double patenting over the claims of U.S. Patent No. 5,563,165. The patent-in-suit in this appeal is U.S. Patent No. RE 44,048, which is a reissue of the '068 patent.

STATEMENT OF THE ISSUE

Whether the plaintiffs-appellants' intentional choice to file a continuation-in-part application instead of a divisional application is correctable by reissue under 35 U.S.C. § 251.

COUNTER-STATEMENT OF THE CASE

A. Introduction

Having enjoyed their patent monopoly on their blockbuster drug Celebrex®, plaintiffs-appellants G.D. Searle LLC and Pfizer Asia Pacific Pte. Ltd. (together Pfizer) hoped to extend their monopoly for an additional 18 months through assertion of a method-of-use patent. After this Court invalidated U.S. Patent No. 5,760,068 (the '068 patent) for obviousness-type double-patenting because it was a continuation-in-part application (CIP) rather than a divisional application, Pfizer attempted to resurrect it through reissue under 35 U.S.C. § 251, although failure to file a timely divisional application is not correctable on reissue. The United States District Court for the Eastern District of Virginia (Arenda L. Wright, U.S.D.J.) granted defendants-appellees' motion for summary judgment invalidating U.S. Patent No. RE 44,048 (the '048 patent). *G.D. Searle LLC v. Lupin Pharms., Inc.*, Case No. 2:13-cv-00121-AWA-LRL, slip op. at 1-16 (E.D. Va. Mar. 12, 2014), A00004-A00020.

Judgment below was entered May 8, 2014. A00001-A00003. Plaintiffs-appellants timely filed their notice of appeal May 16, 2014.

This brief is submitted by defendants-appellees Lupin Pharmaceuticals, Inc. (Lupin), Apotex Inc. and Apotex Corp. (together Apotex). We incorporate by

reference the brief submitted by defendant-appellee Teva Pharmaceuticals USA, Inc. (Teva).

B. The Celebrex® Patents

Pfizer's U.S. Patent No. 5,466,823 (the '823 patent) and U.S. Patent No. 5,563,165 (the '165 patent), directed to the compound and composition of Celebrex®, respectively, expired November 30, 2013, with pediatric exclusivity expiring May 30, 2014. A03656-A03657, A04160-A04162. Pfizer had also obtained a separate method of use patent, the '068 patent. Its history is complex and described more completely below, but this Court in an earlier decision found that it was a CIP of U.S. Patent Application No. 08/160,594 (the '594 application) and, therefore, not protected by the safe harbor provisions of 35 U.S.C. § 121 and thus invalid for obviousness-type double-patenting. *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353, 1358-63 (Fed. Cir. 2008) (*Pfizer I*); *see also* A03733. In response, Pfizer sought reissue of the '068 patent to convert its patent application to a divisional application of the '594 application. A03733-A03734. After several rejections because failure to file a timely divisional application is not correctable through reissue, the application was allowed as the '048 patent, the patent at issue in this litigation. A03977-A03984, A04010-A04017, A04061, A04072.

C. The Prosecution History Leading to the '068 Patent as a CIP

In 1993, Pfizer filed the '594 application with claims directed to compounds, compositions, and methods of use concerning the compounds, which included celecoxib. A04255-A04374. Pfizer then filed U.S. Patent Application 08/223,629 (the '629 application), also directed to compounds, compositions, and methods of use, as a CIP application of the '594 application because it contained new matter. A03659. Subsequently, during the prosecution of the '594 application, the examiner issued a restriction requirement requiring election among three categories of claims. A06570-A06573. Pfizer chose to prosecute the compounds and that patent issued as the '823 patent. A03656. Pfizer filed a divisional application for the composition claims and that patent issued as the '165 patent. A03657, A01727. Pfizer did not file a divisional application for the method of use claims. A03657-A03658.

Pfizer filed another CIP of the '629 application when it filed International Patent Application No. PCT/US94/12720 (the PCT '720), which contained new matter and claims for compounds, compositions, and methods of use. A03730-A03731, A03867-A03959. The PCT '720 is, as Pfizer stated to the district court, a "universal international application," which allowed Pfizer to prosecute it in "multiple countries." A08901-A08902. The PCT '720 application was prosecuted as the national stage U.S. Patent Application No. 08/648,113 (the '113 application)

in the United States. Pfizer admits that the '629 application, the PCT '720 application, and the national stage '113 application are all CIPs containing new matter, which it intentionally included. A03657-A03658, A03730-A03733. As Pfizer's counsel described to the district court:

> Pfizer in prosecuting that ['113 application] did not make it purely a subdivision of the '594 application, which would have made it a divisional. Rather Pfizer put more in that application. Things had happened, new compounds had been invented and so Pfizer put together with method of treatment claims, they put compound, composition and method of treatment claims together but it included subject matter that had been restricted out, the method claims that had been restricted out of the '594 application.

A08902. *See also* Brief of Plaintiffs-Appellants G.D. Searle LLC and Pfizer Pacific Pte. Ltd. (Blue Br.) at 5; A09092-A09093, A09100 ("Pfizer then chose to prosecute the method of treatment claims in a CIP"), A03659, A03662-A03663. Additionally, in prosecuting the '113 application, Pfizer sought and obtained additional claims, not in the PCT '720 application, including a claim for the method of treating colorectal cancer. A02279-A02280, A02282, A03847, A03732-A03733.

Pfizer refers to the self-serving testimony of its former attorney and employee, asserting that he did not intentionally relinquish the safe harbor in filing the '113 application as a CIP. Blue. Br. at 24, citing A07122. Pfizer concedes, however, that when it filed the '113 application, it intentionally did so to take

advantage of the new matter, including, for example, the new compounds it invented since the filing of the '594 application. A08901-A08902. *See also* Blue Br. at 5. Thus, there is no dispute that Pfizer intentionally filed a CIP to gain the benefit of new matter not in the '594 application.

D. The Federal Circuit Invalidated the Asserted Claims of the '068 Patent for Obviousness-Type Double Patenting Over the '165 Patent

Pfizer asserted claims 1-4 and 11-17 of the '068 patent, among others, against Teva in Civil Action No. 04-754 (JCL) (D.N.J.). A06014-A06016, A06028-A06029. The Federal Circuit held that the asserted claims of the '068 patent were invalid for obviousness-type double patenting because the claims were not patentably distinct from the claims of the '165 patent. *Pfizer I*, 518 F.3d at 1358-63. Pfizer was not entitled to the "safe harbor" of 35 U.S.C. § 121 because the '113 application was a CIP, not a divisional application. *Id*. at 1362.

E. Reissue Proceedings Permitted Pfizer to Correct a Non-Correctable Error and Change the CIP Application to a Purported Divisional Application

After this Court's 2008 decision, Pfizer sought reissue of the '068 patent and filed U.S. Patent Application No. 12/205,319 (the '319 reissue application), which purported to be a divisional of the '594 application eligible for the safe harbor of section 121. A03733-A03734. When Pfizer filed the '319 reissue application, it claimed that its deliberate prosecution strategy of filing a CIP and adding new

matter constituted "errors" correctable through reissue, now entitling Pfizer to a divisional application and thus to the safe harbor of section 121. A03970, A06748. The U.S. Patent and Trademark Office (PTO) found that these were not "errors" correctable by reissue under section 251, because failure to file a timely divisional application cannot be corrected by reissue. A03977-A03984, A04010-A04017. After two rejections on this basis, Pfizer then asserted that other errors existed in the '068 patent which allegedly caused the claims in the '068 patent to be indefinite. A04022-A04026. The PTO then ignored its own regulation, *see* 37 C.F.R. § 1.325, and permitted Pfizer to amend the application as a divisional application based on its new position that these claims were indefinite. A04061, A04072.

F. The Decision Below

The district court granted summary judgment invalidating the '048 patent as an improper reissue and for obviousness-type double-patenting. A00012-A00019. The district court found that Pfizer's intentional conduct in prosecuting the '068 patent as a CIP was not an "error" that could be corrected through reissue under section 251. A00013-A00015. The district court agreed with Lupin and Apotex that failure to file a divisional application is not correctable via reissue as a matter of law and that intentional acts are not correctable by reissue. A00012-A00016.

The district court began by looking to the statute defining the errors which may be corrected through reissue, emphasizing that they are limited to "a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent." A00009, quoting 35 U.S.C. § 251(a). Noting that the reissue statute is "remedial in nature," the district court recognized this Court's admonition that "it 'was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application.'" A00009, quoting *In re Weiler*, 790 F.2d 1576, 1579, 1582 (Fed Cir. 1986). It noted that while the patent is entitled to the statutory presumption of validity, "[i]f a reissue patent fails to meet the reissue requirements, it is invalid." A00010, citing *N. Am. Container, Inc. v. Plastipak Packaging, Inc.,* 415 F.3d 1335, 1349 (Fed. Cir. 2005).

The district court followed the consistent holdings of this Court that "the failure to file a divisional application, regardless of the propriety of the underlying restriction requirement, is not an error correctable by reissue under 35 U.S.C. § 251." A00012, quoting *In re Watkinson*, 900 F.2d 230, 231 (Fed. Cir. 1990)*, In re Doyle,* 293 F.3d 1355, 1358 (Fed. Cir. 2002), and *Weiler*, 790 F.2d at 1582. The district court also noted that the PTO "repeatedly took the position that the failure to file a divisional was not correctable via reissue" during the prosecution of the '048 patent. A00012.

The district court also found that the prohibition against correcting a failure to file a divisional through reissue could not be circumvented by assertion of another error, which may be separately corrected under section 251. A00013. Rejecting plaintiff's argument that once one error under section 251 is found, all other errors can be corrected, the district court held that "[p]atent law is not so forgiving." *Id*. The district court quoted the U.S. Patent Office's Manual of Patent Examining Procedure (MPEP) as providing that when more than one error is specified in the declaration supporting reissue, only "any remaining error *which is an error under 35 U.S.C. § 251* will still support the reissue." A00013, quoting MPEP § 1414.II(B) (emphasis in opinion). It also cited case law that once a basis for reissue is found, only "*narrowing changes to the patent's claims* can be made without explanation." A00013, quoting MPEP § 1414.II(B) and *Schering Corp. v. Mylan Pharms., Inc.*, 2012 WL 1473329, *16 (D.N.J. Apr. 27, 2012) (emphasis added in opinion).

Because Pfizer could not amend its application from a CIP to a divisional application and there was neither an error correctable under section 251 nor a narrowing change, the district court rightly concluded that "[t]he '048 patent must be deemed invalid . . . for failure to file a divisional." A00013; *see also, e.g., Watkinson*, 900 F.2d at 231; *Weiler*, 790 F.2d at 1582.

As a second basis for invalidation as an improper reissue, the district court also found that intentional acts cannot be corrected through reissue. A00013-A00016. The district court found that Pfizer's "intentional decision to file a CIP bestowed the benefit of an extended period of exclusivity as to celecoxib." A00015. It rejected Pfizer's argument that "error" should be construed liberally, noting that this Court's predecessor has soundly rejected that position. *Id*. The district court instead applied the proper standard. Citing *In re Serenkin*, 479 F.3d 1359, 1364-65 (Fed. Cir. 2007)*, Miller v. Bridgeport Brass Co.*, U.S. 350, 355 (1881), and *In re Orita*, 550 F.2d 1277, 1281 (C.C.P.A. 1977), the court held that "intentional acts are not correctable via reissue" and therefore found the '048 patent invalid as an improper reissue. A00015.

The district court then found that because the '048 patent cannot properly be designated as a divisional application, the safe harbor of 35 U.S.C. § 121 does not apply and therefore the patent is invalid for obviousness-type double-patenting. A00016-A00019, *see also* A03649 (in response to requests for admission during discovery, Pfizer conceded that the asserted claims of the '048 patent are not patently distinct over the claims of the '165 patent). In response to Pfizer's argument that deference should be given to the PTO's allowance of the reissue as a divisional, the district court properly noted that "the Federal Circuit has counseled that it is a question of law as to whether a patent is invalid for violating the reissue

statute or for double patenting." A00018, citing *Serenkin*, 479 F.3d at 1361 and *Pfizer I*, 518 F.3d at 1363.

SUMMARY OF ARGUMENT

The district court did not err in concluding that Pfizer's reissue patent was invalid because the patent was reissued in contravention of 35 U.S.C. § 251. Pfizer first sought reissue of the '068 patent after this Court invalidated the patent in *Pfizer I*. In that case, the '068 patent was held invalid on obviousness-type double patenting grounds; central to that holding was the determination that because the '068 patent was filed as a CIP rather than as a divisional application, the safe harbor provision of 35 U.S.C. § 121 (which, if applicable, would have protected the '068 patent from invalidation on obviousness-type double-patenting grounds) did not apply. Regretting its decision to include the new matter in the '068 patent that made it a CIP, Pfizer sought reissue to remove the new matter and convert the application to a divisional application.

Citing cases such as *In re Orita*, 550 F.2d 1277 (C.C.P.A. 1977), the PTO correctly rejected Pfizer's argument that reissue was available to relieve Pfizer of the consequences of its decision to file the '068 patent application as a CIP and not as a divisional. A03977-A03984, A04010-A04017. It was only after Pfizer identified to the PTO another error actually correctable by reissue that the PTO relented and permitted Pfizer to use reissue to delete the new matter from the '068

patent and recharacterize it as a divisional application. A04022-A04026, A04072. However, in so doing, the PTO overlooked one of its own regulations, 37 C.F.R. § 1.325, which effectively prohibited the PTO's action because it limits the corrections available in reissue proceedings to errors properly correctable under section 251.

The decisive issue here thus is whether Pfizer's decision to file a CIP rather than a divisional application is an error correctable by reissue under section 251.

Section 251 limits the types of errors which can be corrected by reissue, and an intentional-but-now-regretted decision to include new matter in the '068 patent is not one of those errors. Pfizer complains in its brief that it did not foresee the consequences of its decision, but that complaint (if indulged) would represent an ill-defined expansion of the right to reissue beyond the precedent of this Court. Decisions such as *In re Serenkin*, 479 F.3d 1359, 1364-65 (Fed. Cir. 2007), and *Orita*, 550 F.2d at 1280-81, establish that reissue may not be used to change an intentional strategic decision made during prosecution of a patent, even if that decision turned out in retrospect to have unfortunate consequences or resulted in invalidation of claims. As this Court also held in cases such as *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556 (Fed. Cir. 1989), and *In re Weiler*, 790 F.2d 1576, 1579, 1582 (Fed Cir. 1986), reissue is not a second opportunity for an applicant to prosecute his application again. Thus, errors which could not be

corrected under 35 U.S.C. § 251 cannot be corrected through reissue even if another, correctable error is found.

On this appeal, Pfizer seeks to disturb what has already been settled. Decisions such as *Orita*, 550 F.2d 1277, and *Weiler*, 790 F.2d 1576, long ago settled that a patentee may not use the reissue procedure to correct a mistake in failing to file a divisional application while the parent application was pending. What Pfizer is proposing on this appeal is not only a result inconsistent with those decisions, but a result inconsistent with the requirement of section 121 that a divisional application be copending with the patent application from which it was divided.

In short, Pfizer is attempting a retroactive remaking of the '068 patent that is inconsistent with both precedent and the statutory scheme. The district court recognized as much, and its decision should be affirmed.[1]

ARGUMENT

I. THE '048 PATENT IS AN INVALID REISSUE BECAUSE PFIZER'S STRATEGIC DECISION TO FILE A CONTINUATION-IN-PART INSTEAD OF A DIVISIONAL APPLICATION IS NOT AN ERROR THAT CAN BE CORRECTED THROUGH REISSUE

Not all mistakes made during prosecution of a patent can be corrected; not all bad decisions can be undone. Those errors which can be corrected through

[1] Defendants-Appellees do not disagree with the standard of review as set out in Pfizer's brief. This Court reviews the district court's grant of summary judgment de novo. Blue Br. at 19; Fed. Cir. Rule 28(b).

reissue are defined by statute; failure to file a timely divisional application, and an intentional strategic decision to add new matter to an application, are not correctable through reissue.

Pfizer concedes that it intended to file a CIP rather than a divisional application, which gave it the benefit of an expanded scope and later patent expiration date. Its "error" was neither "a defective specification" nor "claiming more or less" than it could, as permitted by 35 U.S.C. § 251, but that it did not expect or intend that its strategy would have the result of invalidating the patent. Unfortunately for Pfizer, this so-called "error" cannot be corrected under section 251. As the district court correctly held based on Federal Circuit precedent, the '048 patent is invalid because it is an improper reissue.

"Reissue is an extraordinary procedure and must be adequately supported by the circumstances detailed in 35 U.S.C. § 251 (1976) and in the implementing regulations, 37 C.F.R. § 1.175 (1982)." *Ball Corp. v. United States*, 729 F.2d 1429, 1435 (Fed. Cir. 1984) (holding applicant was not precluded from obtaining a reissued patent based on an under-claiming error). Section 251 permits reissue for only two well-defined categories of errors:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the

> payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent.

35 U.S.C. § 251.

Section 251 requires two errors; "(1) error in the patent, and (2) error in conduct." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1564 (Fed. Cir. 1989). This Court has explained the approach to reissue: "While we have acknowledged that § 251 is 'based on fundamental principles of equity and fairness, and should be construed liberally,' we have also stated that the remedial function of the statute is not without limits." *In re Serenkin*, 479 F.3d 1359, 1362 (Fed. Cir. 2007) (internal citation omitted) (quoting *In re Weiler*, 790 F.2d 1576, 1579 (Fed Cir. 1986)). "The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application." *Weiler*, 790 F. 2d at 1582.

A. Pfizer's Failure To File a Timely Divisional Cannot Be Cured By Reissue

Pfizer's argument that it should be permitted through reissue to correct its failure to file a divisional application in a timely fashion is not supported by any prior decisions of this Court. This Court's position has been quite clear that failure to file a timely divisional application is not the kind of error that can be corrected

under section 251.[2] As this Court has held repeatedly, the reissue statute does not permit an applicant to go back in time and file a divisional application when the applicant has failed to do so before the parent application issued. *See, e.g., Weiler,* 790 F.2d at 1582 (acquiescence in restriction requirement and failure to file divisional application forecloses ability to claim subject matter and cannot be corrected by reissue); *In re Orita*, 550 F.2d 1277, 1281 (C.C.P.A. 1977) (applicants forgot to file a timely divisional application, which "exemplifies a mistake which this section [section 251] cannot cure."); *In re Watkinson*, 900 F.2d 230, 231 (Fed. Cir. 1990) (applicant did not file divisional because of mistaken belief that invention was not patentable; "failure to file a divisional application, regardless of the propriety of the underlying restriction requirement, is not an error correctable by reissue under 35 U.S.C. § 251"); *see also In re Doyle,* 293 F.3d 1355, 1358 (Fed. Cir. 2002) ("failure to file a timely divisional in response to a restriction requirement is not an error correctable by reissue," but error in failing to present linking claim in response to restriction requirement may be corrected by reissue).

In addition to falling outside of the errors defined by the statute, a reissue to correct the failure to file a timely divisional application also would violate the copendency requirement of section 121. As this Court's predecessor stated,

[2] The PTO agreed throughout the prosecution of the '048 patent that failure to file a timely divisional application could not be corrected through reissue. A00012, citing A03980-A03982, A04010-A04017.

"[s]hould appellants prevail, the copendency requirement would become meaningless, for should an applicant fail to file a divisional application while maintaining copendency as required by section 120, he could simply revert to section 251 in order to cure his mistake." *Orita*, 550 F.2d at 1281.[3]

Pfizer next argues that it satisfied the copendency requirement because its CIP was prosecuted during the pendency of the parent '594 application, Blue Br. at 32, but this argument abrogates the copendency requirement while ignoring the plain language of the statute. Section 121 requires a divisional application – not just any application – to be filed during the pendency of the patent application. 35 U.S.C. § 121 ("If the other invention is made the subject of a *divisional* application which complies . . .") (emphasis added). The '113 application is a CIP, not a divisional. This Court already has rejected the argument that the reference to a "divisional application" in section 121 includes a CIP. *Pfizer I*, 518 F.3d at 1360-62. That, standing alone, defeats Pfizer's claim on this appeal.

[3] Pfizer argues that its error falls within the language of section 251 because, since the specification claimed priority as a CIP, its decision to file a CIP instead of a divisional is "a defective specification" that resulted in its claiming "more . . . than he had a right to claim" in the sense that it invalidated the patent. Blue Br. at 21-22. The cases hold, however, that the "claiming more or less than he had a right to claim" language in section 251 refers to the scope of the claim and not any statement in the specification that invalidates the patent. *See, e.g., Hewlett-Packard,* 882 F.2d at 1564-65.

Pfizer attempts to distinguish the cases holding that reissue cannot correct a failure to file a timely divisional by arguing that, in contrast, its error was the decision to file a CIP and that the cases do not say (in so many words) that a decision to file a CIP is not correctable through reissue. Blue Br. at 32-34. Since the fact that Pfizer chose to proceed by CIP is merely another way of saying that it decided not to file a divisional (which cannot be corrected through reissue), Pfizer's argument is a distinction without a difference. In other words, Pfizer does not actually distinguish these cases, it merely disagrees with their holdings.

B. Pfizer's Intentional Strategic Decision During Prosecution, Even If Wrong, Cannot Be Corrected on Reissue

The district court correctly held that Pfizer's "intentional acts are not correctable via reissue." A00016. It properly rejected Pfizer's argument that an "error of judgment" or "to choose wrongly" qualifies as an "error" under section 251. A00015 (citing *Serenkin*, 479 F.3d at 1364-65; *Miller v. Bridgeport Brass Co.*, U.S. 350, 355 (1881); *Orita*, 550 F.2d at 1281).

Pfizer further argues that if an outcome is not as intended, then the applicant's decision is a correctable error under section 251. Blue Br. at 23-24. This is wrong for at least three reasons. First, Pfizer's argument cannot be reconciled with prevailing precedent that strategic decisions which are later regretted cannot be undone through reissue. Second, to hold an error of judgment as correctable under section 251, ignores the plain language of the statute. Third,

from a policy perspective, Pfizer's interpretation results in an unlimited statute, as almost any adverse validity ruling could be cured through reissue.

This Court has held otherwise, ruling that "the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251." *Serenkin*, 479 F.3d at 1362. In *Serenkin*, the applicant submitted additional drawings after the original filing date. Offered a choice between retaining the original filing date without the drawings or incorporating them into the application with a new filing date, Serenkin accepted the new filing date. *Id*. at 1361. He later sought reissue to obtain the benefit of the original filing date, asserting that the decision was "an error of judgment" and his attorney "made the wrong procedural choice." *Id*. at 1361, 1362. This Court held that an applicant who made a decision "in exchange for a benefit, and now is unhappy with his choice" cannot "use the reissue process to undo the consequences of his attorney's conscious decision." *Id*. at 1364, 1365. *See also Weiler*, 790 F.2d at 1582 (no correctable error under section 251 for selecting CIP over divisional where there was "nothing of record remotely indicating that Weiler or his counsel or anyone else ever thought of doing so, or ever intended doing so, or failed to do so only through error."); *In re Mead*, 581 F.2d 251, 257 (C.C.P.A. 1978) (a "conscious choice . . . does not constitute 'error' under § 251.")

This Court recently upheld this principle in *In re Dinsmore*, 757 F.3d 1343, 1347-48 (Fed. Cir. 2014) ("[s]ection 251 often applies to applicants' choices, *i.e.*, their deliberate decisions about what to say in their patents, not just slips of the pen. But not every choice that produces inoperativeness or invalidity by reason of a specification, drawing, or claiming problem (within the meaning of section 251) can qualify. Only choices based on 'error' count"). In *Dinsmore*, the applicants filed a terminal disclaimer to avoid an obviousness-type double-patenting rejection, but inaccurately claimed common ownership. They could not fix this problem through reissue because they intentionally surrendered a possible right (to obtain claims in an independent patent) in exchange for the benefit of avoiding the double-patenting rejection; reissue cannot "reverse a later-regretted choice made in obtaining the original patent." *Id.* at 1348. As noted above, the district court's rejection of Pfizer's similar argument, handed down before *Dinsmore* was published, was based on authority of this Court's predecessor. A00015. *See also In re Serenkin* at 479 F.3d at 1364 ("The distinction is between a genuine error, or mistake, and a deliberate, but subsequently found to be disadvantageous, choice.").

Serenkin is very much like the present case. In *Serenkin*, the applicant attempted through reissue to reverse his decision to include new matter (the drawings) when he learned that the decision to include the new matter (and the concomitant change in the priority date) would invalidate his patent claims. The

putative error in *Serenkin* was the same "error" as here – the patent applicant's decision to add new matter to an application resulted in invalidation of claims in that application. The different reasons why the new matter resulted in invalidation in *Serenkin* and here does not change the nature of the "error." Thus, because the "error" in *Serenkin* was not correctable by reissue, so too is the same "error" not correctable here.

Reissue is a limited dispensation granted by Congress to redress unfairness caused by an applicant's error. There is no more unfairness in denying reissue here than in *Serenkin* because the "error" here is the same as in *Serenkin*, and the result is the same (patent claims invalid due to new matter added to application). Fairness does not change depending on why the new matter invalidates the patent, because the adverse consequence is the same – invalidity. Accordingly, in view of *Serenkin*, reissue is not available here to relieve Pfizer of the adverse consequences of its decision to file a patent application containing new matter.

Pfizer's reliance on *In re Wesseler*, 367 F.2d 838 (C.C.P.A. 1966), and *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511 (Fed. Cir. 2012), for the proposition that a strategic choice may be undone through reissue, Blue Br. at 34-38, is misplaced. *Wesseler*'s holding that the use of the term "error" in the Patent Act of 1952 meant that "inadvertence, accident or mistake" was no longer a requirement under the reissue statute is a misstatement of the law. More recent

Federal Circuit cases have disagreed with *Wesseler* that the change in language meant a change in meaning. *See, e.g.*, *Orita*, 550 F.2d at 1280 ("we have previously concluded that the substitution of 'error' in section 251 for 'inadvertence, accident, or mistake' in former R.S. section 4916 did not involve a substantive change"); *Weiler*, 790 F.2d at 1582 (same); *Mead*, 581 F.2d at 257 ("conscious choice" not to file continuing application not "error"). Indeed, *In re Wadlinger*, 496 F.2d 1200 (C.C.P.A. 1974), a case relied upon by Pfizer, explicitly held that the holding in *Wesseler* was incorrect, 496 F.2d at 1207.[4] In addition, the *Wesseler* court found that – unlike in the instant case – the applicant had not made a strategic decision to limit the scope of the patent claims, but had attempted to protect the full scope while meeting the examiner's objections.

Similarly, the correctable error in *Rosuvastatin* was not an intentional decision to follow a particular strategic course of conduct, but a mistake in failing to file an Informational Disclosure Statement (IDS) identifying additional prior art. This Court agreed with the district court finding that there was no evidence of a deliberate choice to abandon the claimed subject matter, but instead there was an "unintentional failure to file an IDS" as a result of the chaos, confusion and inexperience in the in-house department prosecuting the patent. *Rosuvastatin*, 703

[4] *Wadlinger* involved an error of under-claiming. *See* 496 F.2d at 1202. An under-claiming error is provided for by 35 U.S.C. § 251, although *Wadlinger* itself overstates the scope of the error which may be corrected by suggesting, contrary to the holdings of this Court, that some intentional actions might be correctable error.

F.3d at 523-24. Therefore, the applicant "did not act intentionally to make the error for which it seeks reissue." *Id*. at 524.

Pfizer overstates the breadth of the *Rosuvastatin* ruling, which did not hold that any erroneous attorney action during prosecution may be corrected through reissue, *see* Blue Br. at 34-35, but only that *Serenkin* does not bar correction of attorney action through reissue in appropriate circumstances; "it is appropriate to consider the nature of the action to determine whether it is a correctable error." *Rosuvastatin*, 703 F.3d at 523. Where, as here, the attorney action was the intentional adoption of a strategy intended to confer a benefit on the applicant, it is not a correctable error. Unlike counsel in *Rosuvastatin*, Pfizer's attorneys did "act intentionally to make the error for which it seeks reissue" and therefore its later regret for its choice cannot be fixed through reissue.[5]

C. A Misunderstanding of the Law Is Not Enough to Allow Correction Through Reissue

Pfizer argues that an applicant's "misunderstanding, or even a lack of clarity, about the law" resulting in invalidation of a patent is a sufficient basis for reissue.

[5] Pfizer suggests that reissue is not appropriate only if a claim is surrendered in exchange for a benefit. Blue Br. at 35. The cases are not so narrow. Although the consideration in *Rosuvastatin* included whether a claim had been surrendered, other cases, as discussed above in the text, look to whether the strategy followed was an intentional selection of a perceived benefit. For example, *Serenkin* involved surrender of a priority date in exchange for inclusion of drawings in the application; *Mead* involved a decision to let an application issue with the intention of filing a later application.

Blue Br. at 15-16. Under Pfizer's approach, a finding that a patent was invalid would be merely the first step leading to a reissue, making it a common rather than "extraordinary procedure." *See Ball Corp.*, 729 F.2d at 1435. The cases, including those cited by Pfizer, do not go so far.[6] Pfizer's "error" (that it did not know that a CIP was ineligible for the safe harbor of section 121) is not materially different from the "errors" of other patent applicants who chose one path during prosecution, and then learned later that they had made the wrong decision. It is not relevant that the bad consequences of their chosen strategy came from their misunderstanding of the law. *See In re Whittelsey*, 83 F.2d 894, 897 (C.C.P.A. 1936) ("The fact that appellant was not aware of the change in rule 41 prior to the issue of his patent does not, in our opinion, affect the question before us. It is a familiar rule that ignorance of the law is not an excuse for a course of action").

Pfizer's effort to limit cases like *Serenkin*, where reissue was denied, to only those applicants aware of the potential consequences of their decision does not make much sense; no applicant intentionally selects a course of conduct that it expects will lead to invalidation of its patent. Pfizer suggests that *Serenkin* is not

[6] Pfizer's reading would make superfluous the language in section 251 limiting reissue to specified errors. It is "a cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001); *Chandler v. Shinseki*, 676 F.3d 1045, 1050 (Fed. Cir. 2012). The limitations on the types of "error" in section 251 thus should be given effect.

applicable because in *Serenkin* the examiner alerted the applicant to the potential consequences of its decision. But, as explained below, *Serenkin* should not be read to be limited to situations in which the applicant was aware of the potentially adverse consequences of its decision.

As *Pfizer I* explained, section 121 expressly limits the safe harbor to divisional applications, which were clearly known to Pfizer and its counsel. *Pfizer I*, 518 F.3d at 1362. Pfizer intentionally chose a CIP instead of a divisional application, added new matter, and then attempted to obtain the protection of the safe harbor by asserting that "divisional" in section 121 should be construed (contrary to its normal usage) to encompass CIPs. If, as Pfizer argues, the applicability of section 251 depends upon the subjective opinion of the prosecuting attorney about the limits of the applicable law, then there is no predictability about when reissue may be available. This illustrates the problem with Pfizer's argument – it has no clear limits, and substitutes the ambiguity of subjectivity for the clarity of *Serenkin*.

Pfizer also relies on *Moist Cold Refrigerator Co. v. Lou Johnson Co*., 217 F.2d 39 (9th Cir. 1954), for the proposition that a misunderstanding of the law can support a reissue. Blue Br. at 25-26. But *Moist Cold* exemplifies an "extraordinary" situation, involving a dramatic shift in the law when the Supreme Court overturned the use of functional language in claims. As the *Moist Cold* court

noted, "[t]here can be little doubt that the decision . . . came as something of a surprise to the patent bar." 217 F. 2d at 42. So controversial was the Supreme Court's holding that Congress overruled the case between the time of the decision and the *Moist Cold* ruling. *See* P.J. Frederico, *Commentary on the New Patent Act*, 35 U.S.C.A., at pp. 25-26 (West Publishing Co. 1954 ed.), reprinted in 75 J. Pat. & Trademark Off. Soc'y 161, 186-87 (1993). In addition, the applicant in *Moist Cold* had not made a strategic, deliberate or intentional decision, nor obtained a benefit as a result of its approach to drafting the claims.

Pfizer also cites to *Rohm & Haas Co. v. Roberts Chemicals, Inc*., 245 F.2d 693 (4th Cir. 1957), which involved – as the Fourth Circuit put it – "peculiar circumstances" because the Patent Act of 1952 retroactively changed the law regarding process claims. The issue in *Rohm & Haas* was not whether the patent was invalid, but whether the applicant could rephrase its claims to cover a process within the express terms of the new statute. *Id*. at 699-700.

Moist Cold and *Rohm & Haas* illustrate the high standard and rare circumstances for when a mistake in understanding of the law is correctable by reissue, an exception to the general rule that intentional decisions are not correctable by reissue. In the instant case, Congress did not change the patent laws; instead, this Court in *Pfizer I* merely reaffirmed the plain language of

section 121 that the term "divisional" in section 121 refers to divisional applications, not also CIPs.

Pfizer's assertion that "this Court has acknowledged" that before the decision in *Pfizer I*, the cases "assume[d] that section 121" applied to CIPs, Blue Br. at 23, is an overstatement. This Court in *Pfizer I* noted that Pfizer cited three cases where the Court "although it did not consider the question, may have assumed" this, but it then explained why those cases were not applicable to the question of whether section 121 applied to a CIP. *Pfizer I*, 518 F.3d at 1362.[7] *Pfizer I* also noted that its holding was "consistent with the PTO's understanding of section 121," *id*., so it should not have come as a complete surprise to the patent bar or Pfizer's counsel. Thus, unlike *Moist Cold* and *Rohm & Haas*, Pfizer was not relying on a clear statement of the law during prosecution that changed radically after the patent issued.

The other two cases on which Pfizer relies – *Wadlinger* and *Scripps* – are equally unhelpful to its cause. Blue Br. at 26, 27. In *Wadlinger*, the asserted error was under-claiming because the applicant "did not understand all of the inherent characteristics of the claimed compositions." 496 F.2d at 1202. The applicant had cancelled claims because he could not show unexpected superior results; after the patent issued, he realized he could show those results. This was merely an under-

[7] Pfizer cites these same three cases again to this Court, for the same proposition that the law was changed dramatically by *Pfizer I*. Blue Br. at 24.

claiming error, "one of the most common sources of defects in patents." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1575 (Fed. Cir. 1991) (correcting an under-claiming error due to the "attorney's failure to appreciate the full scope of the invention.").

Finally, Pfizer points to language in *Dinsmore* distinguishing the facts before that Court from cases involving "false or inadequate understanding about then-existing facts or law" which "gave rise to the patenting choice that the reissue is being invoked to correct." Blue Br. at 26, quoting *Dinsmore*, 757 F.3d at 1348. The errors in the cited cases, however, are the usual ones of mistakes in the scope of the claims because of misunderstandings about the process, errors in translation from Japanese, the need for a supplemental declaration, and the like. None involved an intentional selection of a strategy to obtain a benefit – as here, where Pfizer obtained a broader scope – which was later regretted when, in hindsight, the cost of the hoped-for benefit was higher than expected. *Dinsmore* does not hold that reissue is appropriate to correct "a deficient understanding of" law, as Pfizer states (while relying on dicta). Blue Br. at 24. As discussed above, *Dinsmore* held that a defective terminal disclaimer could not be rectified through reissue after the patent issued, and that the applicant's belief that its strategy would work was not an error within the statute. 757 F.3d at 1349.

D. Conclusion

The ability to correct errors through reissue is not unlimited; although an equitable remedy, it is restricted to the errors described in the statute. It is established law that a failure to file a timely divisional is not correctable through reissue and that the consequences of an intentional, strategic decision cannot be avoided through reissue. Since Pfizer intentionally decided not to file a divisional application, it cannot now undo that decision through reissue.

II. EVEN IF ONE FINDS ANOTHER CORRECTABLE ERROR, FAILURE TO FILE A TIMELY DIVISIONAL STILL CANNOT BE FIXED THROUGH REISSUE

The district court's holding that only errors correctable under 35 U.S.C. § 251 may be corrected through reissue follows the letter and spirit of the statute and the case law. Pfizer's argument that it can circumvent the requirements of section 251 by finding an allowable error properly was rejected. *See* Blue Br. at 39-45.

As the district court said, "[p]atent law is not so forgiving." A00013. Pfizer learned that on its first appeal, when this Court held that a statute providing a safe harbor for "divisional" applications meant what it said, and was limited to "divisional," not just any, applications. *Pfizer I*, 518 F.3d at 1360-61. As this Court noted in *Geneva* (cited by Pfizer for another proposition, Blue Br. at 24), "Given the potential windfall such a patent term extension could provide to a patentee, this court applies a strict test for application of § 121." *Geneva Pharms.,*

Inc. v. GlaxoSmithKline, PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003). Although section 121 also is a "remedial" statute, that did not excuse the requirement that the applicant must come "within [its] purview" for it to apply. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.,* 916 F.2d 683, 688 (Fed. Cir. 1990) (cited by Pfizer for another proposition, Blue Br. at 23-24).

Similarly, the remedial purpose of section 251 does not provide an applicant a "second opportunity" to do its prosecution all over again. Its remedial purpose is limited to those errors which fall within its purview, as this Court has held in numerous cases. *E.g., In re Weiler*, 790 F.2d 1576, 1579, 1582 (Fed Cir. 1986); *In re Orita*, 550 F.2d 1277, 1280-81 (C.C.P.A. 1977); *In re Serenkin*, 479 F.3d 1359, 1354-65 (Fed. Cir. 2007).

Pfizer relies on the *Hewlett-Packard* case and quotations from parts of the MPEP to support its argument. Blue Br. at 40-45. But as the *Hewlett-Packard* court held, "reissue is not intended to give the patentee simply a second chance to prosecute the patent application." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1565 (Fed. Cir. 1989), citing and quoting *Weiler*, 790 F.2d at 1582 ("The reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application."); *see also Orita*, 550 F.2d at 1281 ("Section 251 is

not a panacea designed to cure every mistake which might be committed by an applicant or his attorney").

In *Hewlett-Packard*, this Court found that a claim drafting error could not be corrected through reissue because the applicant failed to establish that it was "inadvertent error in conduct," rather than just "[i]nsight resulting from hindsight on the part of new counsel." *Hewlett-Packard Co.*, 882 F.2d at 1565-66. Pfizer's quotation that "[r]eissue is essentially a reprosecution of all claims," *id.* at 1563, Blue Br. at 40, is taken out of context. The *Hewlett-Packard* Court was addressing whether inequitable conduct on the reissue should invalidate not only the reissue claims, but also the carry-over claims. While noting that carry-over claims can be disallowed on reissue, because as a "reprosecution" all claims must be supported, the *Hewlett-Packard* court then held that the reissue claims were invalid for inequitable conduct during the reissue (a fraudulent declaration asserting error), but the original claims survived. *Id.* at 1566-1567. Far from supporting Pfizer's position that anything goes once a reissue is permitted, *Hewlett-Packard* stands for the proposition that reissue is limited.

The rule that only errors correctable pursuant to section 251 may be corrected on reissue (with ministerial exceptions) also is clear from the regulations. 37 C.F.R. § 1.325 provides: "Mistakes other than those provided for in §§ 1.322,

1.323, 1.324,[8] and not affording legal grounds for reissue or for reexamination, will not be corrected after the date of the patent." Pfizer does not assert that its mistake may be corrected by reexamination or through a certificate of correction. The examiner apparently read the MPEP as permitting reissue here, but the MPEP cannot expand the scope of reissue beyond the statute (or the holdings of this Court). *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984); *see also In re Recreative Techs. Corp.*, 83 F.3d 1394, 1398 (Fed. Cir. 1996) ("when a section of the M.P.E.P. is inconsistent with the statute it must yield to the legislative purpose."). Thus, 37 C.F.R. § 1.325, which is consistent with the reissue statute, controls.[9]

Pfizer concedes that section 1.325 "lists the avenues available for correcting errors." Blue Br. at 43 n.10. It does not distinguish this regulation, just asserts that appellees "read[] too much into that provision." *Id.* Pfizer does not suggest another interpretation of the regulation. *Id*. Instead, it points to the location of the

[8] Sections 1.322 and 1.323 provide bases to correct a patent with a certificate of correction based on a mistake made by the PTO or the applicant, respectively. *See also* 35 U.S.C. §§ 254-255. Section 1.324 provides a basis to obtain a certificate of correction concerning the inventors named in the patent. *See also* 35 U.S.C. § 256. Certificates of correction are used for minor or clerical mistakes. MPEP § 1481, *see also* 35 U.S.C. § 255.

[9] In permitting Pfizer to correct errors that are not correctable, the PTO ignored its own regulation. *Thuron Indus., Inc. v. Conard-Pyle Co.*, 579 F.2d 633, 637 (C.C.P.A. 1978) ("Like any government agency, the PTO is bound by, and may not ignore, its own rules.")

regulation within the MPEP. *Id*. If a manual cannot amend a statute, however, certainly the organization of the manual does not amend the statute.[10] Similarly, Pfizer does not explain why the MPEP limitation cited by the district court, that only an error specified in the declaration "*which is an error under 35 U.S.C. § 251* will still support the reissue," A00013, quoting MPEP § 1414.II(B) (emphasis in opinion), also does not contradict its theory.

Case authority discussed above makes clear that there are certain errors that are not correctable either by reissue or by a certificate of correction. The error here – the intentional decision not to file a divisional application but instead to take advantage of new matter in a CIP – is one of those errors that cannot be corrected.

Permitting Pfizer to rewrite history and turn a CIP into a divisional application would permit Pfizer to "circumvent" the copendency requirements of 35 U.S.C. § 121. *See Orita*, 550 F.2d at 1280-81; *see also In re Yamazaki*, 702 F.3d 1327, 1333 (Fed. Cir. 2012) (reissue cannot nullify terminal disclaimer requirement). The fact that Pfizer was able to identify another mistake in the '068 patent (which had gone unnoticed throughout the previous litigation and much of the reissue prosecution) does not nullify the requirements of section 251 nor,

[10] The omission of 37 C.F.R. § 1.325 from a portion of the MPEP focused on regulations directed only to reissue might explain why the patent examiner (and apparently Pfizer's counsel) missed its prohibition against reissue here. The rule was not cited during the reissue prosecution.

through unwarranted expansion of that statute, the requirements of the section 121 safe harbor.

Section 251, as a matter of equity, provides an exception to permit corrections in the specified situations provided in the statute. "[T]he reissue statute 'is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally.' . . . Yet 'the remedial function of the statute is not without limits." *Yamazaki*, 702 F.3d at 1333. The limited reach of the statute is clear, and the necessity of coming within its requirements has been upheld by this Court. Any other result would make a mockery of the requirements of section 251 and, contrary to the holdings of this Court, would turn it into a "second opportunity to prosecute *de novo* his original application." *Weiler*, 790 F.2d at 1582; *see also Hewlett-Packard Co.*, 882 F.2d at 1565-66; *Orita*, 550 F.2d at 1280-81.

Pfizer's argument that the conversion to a divisional application should be allowed because the statute does not specifically exclude making otherwise-impermissible corrections once reissue is allowed, Blue Br. at 39-45, simply ignores 37 C.F.R. § 1.325, which expressly precludes any correction not specifically allowed by statute. Similarly, Pfizer's argument that the district court misread *Schering Corp. v. Mylan Pharmaceuticals, Inc.*, 2012 WL 1473329 (D.N.J. Apr. 27, 2012), because an express permission to narrow claims and a prohibition on broadening claims does not also state that requirements of section

251 must be followed even if one error is identified, is backwards. It is not enough for Pfizer to say that it cannot find an express prohibition for its conduct; it must find permission. Section 251 is not an exception to an otherwise unbounded right to make any changes through reissue; it is an exception that permits only certain errors to be rectified. There is nothing inequitable or unfair about Pfizer's being held to the consequences of its decisions, even if in retrospect it wishes it had made other choices.

Relying on 37 C.F.R. § 1.175, MPEP §§ 1402, 1414.II, and *Schering Corp.*, 2012 WL 1473329 at *16, Pfizer has argued that it is permitted to correct "errors" that are not correctable because it identified other errors that are correctable in a declaration. Blue Br. at 41-44. However, *Schering*, the regulation, and the MPEP merely stand for the uncontroversial proposition that not every "error" sought to be corrected requires explanation. Even though a patentee need not identify and explain all errors that it corrects on reissue, anything corrected must be permissibly correctable under the statute. *See* 35 U.S.C. § 251; 37 C.F.R. § 1.325; *Serenkin,* 479 F.3d at 1364-65.

Pfizer cites no cases which allowed an applicant to correct on a reissue something that otherwise was not a correctable error, and we have found none. Since Pfizer's error is not correctable under section 251, as discussed above, it cannot fix the problem through the back door by finding another correctable error.

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

/s/ Douglass C. Hochstetler
Douglass C. Hochstetler
Kelley Drye & Warren LLP
333 West Wacker Drive
Chicago, Illinois 60606
(312) 857-7070

Beth D. Jacob
Clifford Katz
Kelley Drye & Warren LLP
101 Park Avenue
New York, New York 10178
(212) 808-7800

Attorneys for Defendant-Appellee Lupin Pharmaceuticals, Inc.

/s/ Stephen R. Auten
Stephen R. Auten
Richard T. Ruzich
Ian Scott
Taft Stettinius & Hollister LLP
111 E. Wacker Drive, Suite 2800
Chicago, Illinois, 60601-3713
(312) 527-4000
Attorneys for Defendants-Appellees Apotex Inc. and Apotex Corp.

PROOF OF SERVICE

Form 30

FORM 30. Certificate of Service

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on Sep 25, 2014 by:

- ☐ US mail
- ☐ Fax
- ☐ Hand
- ☒ Electronic Means (by email or CM/ECF)

Clifford Katz
Name of Counsel

/s/ Clifford Katz
Signature of Counsel

Law Firm: Kelley Drye & Warren LLP
Address: 101 Park Avenue
City, State, ZIP: New York, New York 10178
Telephone Number: 212-808-7800
FAX Number: 212-808-7897
E-mail Address: ckatz@kelleydrye.com

NOTE: For attorneys filing documents electronically, the name of the filer under whose log-in and password a document is submitted must be preceded by an "/s/" and typed in the space where the signature would otherwise appear. Graphic and other electronic signatures are discouraged.

Form 19

FORM 19. Certificate of Compliance With Rule 32(a)

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or Federal Rule of Appellate Procedure 28.1(e).

☑ The brief contains [*8600*] words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), or

☐ The brief uses a monospaced typeface and contains [*state the number of*] lines of text, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Appellate Procedure 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

☑ The brief has been prepared in a proportionally spaced typeface using [*Microsoft Word 2010*] in [*14 pt. Times New Roman*], or

☐ The brief has been prepared in a monospaced typeface using [*state name and version of word processing program*] with [*state number of characters per inch and name of type style*].

/s/ Clifford Katz

(Signature of Attorney)

Clifford Katz

(Name of Attorney)

Appellee Lupin Pharmaceuticals, Inc.

(State whether representing appellant, appellee, etc.)

September 25, 2014

(Date)

Reset Fields